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10/642,455	08/15/2003	Hasmukh B. Patel		2183

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EXAMINER
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SCHLIENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## **NON-FINAL OFFICE ACTION**

Claims 1-3 are pending. No claims is allowed.

### ***Arrangement of the Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Content of Specification***

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: Not Applicable
- (c) Statement Regarding Federally Sponsored Research and Development: Not Applicable
- (d) The Names Of The Parties To A Joint Research Agreement: Not Applicable
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: Not Applicable
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
  - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of

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the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing, Not Applicable

### ***Small Entity Status***

1. This application may qualify for "Small Entity Status" and, therefore, applicant may be entitled to the payment of reduced fees. In order to establish small entity status for the purpose of paying small entity fees, applicant must make a determination of entitlement to small entity status under 37 CFR 1.27(f) and make an assertion of entitlement to small entity status in the manner set forth in 37 CFR 1.27(c)(1) or 37 CFR 1.27(c)(3). Accordingly, if applicant meets the requirements of 37 CFR 1.27(a), applicant must submit a written assertion of entitlement to small entity status under 37 CFR 1.27(c) before fees can be paid in the small entity amount. See 37 CFR 1.27(d). The assertion must be signed, clearly identifiable, and convey the concept of entitlement to small entity status. See 37 CFR 1.27(c)(1). No particular form is required.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

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It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Please refer to attached Oath or Declaration for an example.

***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention is directed to nonstatutory subject matter. Claim 3 is drafted in terms of "The use of", however "The use of" is not one of the statutory classes of invention. *Clinical Products v. Brenner*, 1449 USPQ 475, 476 (1996).

Examiner suggests that the Applicant redraft claim 3 to accord with current US practice. Applicant is kindly requested to see the examples on page 10 of this office action.

5. Claim 3 is also rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility or a well established utility. In claim 3 it is asserted that choline ester derivatives can be used in the treatment of cognitive disorders, including Alzheimer's disease and Down Syndrome. With respect to Alzheimer's disease, one skilled in the art knows that the disease has no known cure, no known cause or mechanism, and can not even be definitively assigned as a differential diagnosis in the absence of a post mortem examination. It is also well known in the art that Down Syndrome is currently

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untreatable, however, treatment of symptoms associated with Alzheimer's disease and Down Syndrome have been well established.

Claim 3 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. **Claim 3 is being construed as a method claim for examination purposes.**

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 are directed to choline ester derivatives and their use in treatment of several cognitive disorders. The specifications don't teach one skilled in the art how to obtain the claimed invention, nor does it teach how to use the claimed invention. It is unclear if the Applicant was in possession of the invention at the time of filing.



The Applicant failed to provide written description of the invention. There is no description of how to make the choline ester derivatives, nor is there any description of how to adequately test these derivatives against the said cognitive disorders.

9. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **enablement** requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the nature of the invention
- 2) the state of the prior art
- 3) the relative skill of those in the art
- 4) the predictability of the art
- 5) the breadth of the claims
- 6) the amount of direction or guidance provided
- 7) the presence or absence of working examples
- 8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

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### **The nature of the invention**

The claims are drawn to choline ester derivatives and their use in the treatment of the various cognitive disorders:

- Alzheimer's disease
- Down Syndrome
- Central Nervous System (CNS) disorders
- Peripheral Nervous System (PNS) disorders
- Memory-related disorders
- Enhancements of memory and related function
- Enhancement of CNS functions
- Enhancements of PNS function
- Improvement of cognition
- Improvement in learning and behavior

### **The predictability of the art**

There is lack of predictability in the art especially in the treatment of Alzheimer's disease, Down Syndrome, and Central Nervous System disorders. The National Institutes of Neurological Disorders and Stroke state on their website (see attached document) "There is no cure for AD [Alzheimer's disease] and no way to slow the progression of the disease." Down syndrome is a set of mental and physical symptoms that result from having an extra copy of Chromosome 21. The National Institutes of Health state that Down Syndrome is not a condition that can be cured (see attached document). CNS disorders is a generic term that encompasses a variety of disorders, for example Parkinson's disease. Parkinson's disease results from the loss of neurons in the substantia nigra pars compacta, and similarly has no known cure. "Current Parkinson's disease medications treat symptoms; none halt or retard dopaminergic neuron degeneration" (Dauer et al, see the abstract, especially col. 1 lines 1-4; see also

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Introduction, especially col. 2 lines 1-3). The disclosure provides no indication that the claimed compounds are efficacious in treating any of these claimed disorders. One skilled in the art would not be able to practice the instantly claimed invention, since no description is found of an actual compound or method of use. Therefore, it is impossible to predict the treatment of the various cognitive disorders listed in claim 3.

Also, the recitation of "derivatives", with regards to the choline ester compounds, in claim 1 encompasses a plethora of compounds, wherein determining the toxicity and efficacy of all such compounds for use *in vivo* requires undue experimentation. Therefore, it is impossible to predict the efficacy of the compositions as in claims 1 and 2.

### **The breadth of the claims**

The claims are drawn to choline ester derivatives, which can encompass a plethora of compounds. In light of the specifications, the recitation of derivatives can be any chemical moiety attached to a choline moiety through an ester linkage. Given the broadest reasonable interpretation of the claims, this recitation of derivatives can encompass countless numbers of chemical moieties. The claims are also drawn to the use of the choline ester derivatives in the treatment of several cognitive disorders.

6) the amount of direction or guidance provided

The claims are drawn to choline ester derivatives and their use in the treatment of various cognitive disorders and there is no guidance in the specifications for one skilled in the art to practice the invention. The Applicant fails to teach anyone skilled in

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the art how to make the compounds as in claims 1 and 2, nor how to use these compounds in treatments of the cognitive disorders as in claim 3.

### **The quantity of experimentation necessary**

Since the nature of the invention is so unpredictable, and there is no direction and/or guidance provided in the disclosure for the reasons cited above, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Again, the first paragraph of 35 U.S.C. 112 states:

*The specification shall contain a **written description** of the invention, and of the manner and process of **making and using** it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

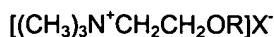
11. Claims 1-3 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited (US Patent 4,963,556, claims 1 and 5 shown below).

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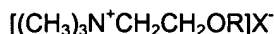
What is claimed is:

1. A pharmaceutical composition for enhancing nasal, buccal, sublingual and vaginal absorption of a formulation comprising a therapeutically effective dosage amount of an antiviral drug and a choline ester absorption enhancing agent of the formula:



wherein R is saturated acyl ( $\text{C}_2\text{-C}_{20}$ ), acyl ( $\text{C}_2\text{-C}_{20}$ ) with 1 to 6 double bonds, hydroxyacyl ( $\text{C}_2\text{-C}_{20}$ ) with 1 to 3 hydroxy groups, ketoacyl ( $\text{C}_4\text{-C}_{20}$ ), unsaturated hydroxyacyl ( $\text{C}_5\text{-C}_{20}$ ), alkylaroyl ( $\text{C}_7\text{-C}_{20}$ ) arylacyl ( $\text{C}_7\text{-C}_{20}$ ), alkylaroyl ( $\text{C}_7\text{-C}_{20}$ ) or carbalkoxyacyl ( $\text{C}_5\text{-C}_{20}$ ) and X is a pharmaceutically acceptable counterion.

5. A method of enhancing the rate of absorption of an antiviral drug administered to the nasal, buccal, sublingual or vaginal cavity, which comprises administering a composition comprising a therapeutically effective dosage amount of said drug and a choline ester absorption enhancing agent of the formula:



wherein R is saturated acyl ( $\text{C}_x\text{-C}_{20}$ ), acyl ( $\text{C}_2\text{-C}_{20}$ ) with 1 to 6 double bonds, hydroxyacyl ( $\text{C}_2\text{-C}_{20}$ ) with 1 to 3 hydroxy groups, ketoacyl ( $\text{C}_4\text{-C}_{20}$ ), unsaturated hydroxyacyl ( $\text{C}_5\text{-C}_{20}$ ), carboxyacyl ( $\text{C}_4\text{-C}_{20}$ ) arylacyl ( $\text{C}_7\text{-C}_{20}$ ), alkylaroyl ( $\text{C}_7\text{-C}_{20}$ ) or carbalkoxyacyl ( $\text{C}_5\text{-C}_{20}$ ) and X is a pharmaceutically acceptable counterion.

12. Applicant is advised that synonyms are not necessary in the claims (as in the instant claims 1 and 2) as long as the invention as claimed can be identified from the given name of the compound.

### ***Contact Information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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